REMARKS

To expedite prosecution, Applicants have amended independent claim 1 to require the expression of both the foreign gene of interest and the Sendai viral genes contained within the Sendai viral genome. Support for this amendment is found in original claims 3 and 14 (both of which are presently canceled). Applicants have also amended independent claim 27 to require the deletion or inactivation of at least one of the NP, P, and L genes as well as the retention of all other Sendai virus genes other than the NP, P, and L genes. Support for this amendment is found in the specification as originally filed, particularly at p. 3, lines 14-16; p. 8, lines 25-27; p. 13, lines 18-21; and p. 15, lines 8-12. Thus, at present, claims 1, 4-13, 15-18, 20, 22, 27, and 28 are pending in the application. Applicants respectfully submit that no new matter has been added.

Applicants respectfully submit that the rejections and objections set forth in the Office Action mailed November 4, 2003 are moot in view of the amendments presented herein. Accordingly, Applicants respectfully request that the Examiner reconsider the outstanding objections and rejections in the in light of the amendments and remarks herein:

Double Patenting Rejections

Applicants note that the instant claims stand provisionally rejected as being obvious in view of the claims of a number of pending applications, many of which were filed after the instant application. M.P.E.P. 706.02(k) states that where two applications of different inventive entities are co-pending and the filing dates differ, a provisional rejection should be made in the later filed application if the applications have a common assignee or a common inventor. Accordingly, the provisional rejections based on the following later filed applications should be withdrawn from this, the earlier filed application: 09/823,699; 09/843,922; 10/111,356; 10/181,646; 10/312,476; 10/316,530; 10/316,535; and 10/444,661. In any event, Applicants will assess the need to file a terminal disclaimer once allowable subject matter has been established in the instant application.

Regarding the obviousness-type double patenting rejection of claims 7-9, 11, 12, 20, and 22 as allegedly being obvious in view of the claims of USPN 6,514,728, contrary to the Examiner's suggestion, the instant claims do not overlap in scope with the patent claims. Specifically, whereas the instant claims are directed to a method for producing a recombinant Sendai viral vector and kit

for performing same, the claims of the '728 patent are directed to a method for producing a cytokine and method components thereof. As such, the two claim sets are patentably distinct. Accordingly, Applicants respectfully submit that the provisional obviousness-type double patenting rejection of claims 7-9, 11, 12, 20, and 22 should be reconsidered and withdrawn.

Rejections Under 35 U.S.C. 102

Claims 1, 3-6, 11-13, and 27 stand rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Park et al. (PNAS USA, 1991).

Applicants respectfully submit that the claim amendments presented herein render these rejections moot. Specifically, with respect to claims 1 *et seq.*, to expedite prosecution, Applicants have incorporated the limitations of claim 14 (indicated as free from prior art) into independent claim 1. Thus, claim 1 as presently pending is directed to a recombinant Sendai viral vector containing a Sendai viral genome carrying a foreign gene, wherein the vector allows for the expression in a host cell of both Sendai viral genes contained within said Sendai viral genome and the foreign gene of interest. Claim 27 has been similarly amended to require the preservation of all other Sendai virus genes, other than genes encoding the NP, P, and L proteins. In contrast, the Park reference discloses the pSend-CAT plasmid in which the coding region of the Sendai virus genome is replaced with the antisense coding region of the CAT gene. As such, the Park plasmid is completely devoid of Sendai virus genes and is incapable of expressing Sendai viral genes.

In order to anticipate a claim, a single reference must disclose each and every element of the claim. As the Park reference fails to disclose or suggest the above-noted claim element, it cannot anticipate the pending claims. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection in view of the amendments and remarks presented herein.

Rejections Under 35 U.S.C. 103

Claims 1, 3-6, 11-13, and 27 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious in view of Hsu et al. (Virology, 1985), Ogura et al. (JGV, 1981), or Middleton et al. (Virology, 1990). According to the Examiner, Hsu teaches Sendai virus genomes with NP, P, or

L deleted or modified, Ogura teaches Sendai virus with a modified P gene, and Middleton teaches Sendai virus genomes with NP, P, and L genes modified.

Again, Applicants respectfully submit that the claim amendments presented herein render these rejections moot. Specifically, claim 27 has been amended to require the deletion or inactivation of at least one of the NP, P, and L genes and the preservation of all other Sendai virus genes, other than genes encoding the NP, P, and L proteins. In contrast, the Sendai virus DI RNA disclosed by Hsu contains only the 3' end of the NP gene and the 5' end of the L gene. In this manner, it is similar to the recombinant virus taught by Park. Since the Hsu particles do not retain all other Sendai viral genes, other than those encoding the NP, P, and L proteins as required by pending claim 27, the Hsu reference can neither anticipate nor render obvious the invention of claim 27.

Likewise, Ogura and Middleton fail to anticipate or render obvious the invention of claim 27. Specifically, Ogura discloses temperature sensitive Sendai virus mutants. The ts mutants showed reduced amounts of RNA synthesis when compared with that of the wild type (HVJo) and were, accordingly, defective in functions required for virus-specific RNA synthesis in replication. However, although the expression level was found to be low, the P gene remained sufficiently intact to yield some level of active P protein. In contrast, claim 27 requires that the NP, P, and/or L genes either be deleted or inactivated. According to the Dictionary of Gene Technology (Gunter Kahl, ed., 1995), excerpts of which are attached hereto, an "active" gene is one that is transcribed into ribosomal RNA, transfer RNA or messenger RNA, whereas a "cryptic" gene (or inactive or silent gene) is one that is not expressed at all. Accordingly, since the Ogura mutants do not involve deletion or inactivation of one or more of the NP, P, or L genes, the Ogura reference can neither anticipate nor render obvious the invention of claim 27.

Middleton discloses Sendai virus mutants having mutation(s) in the genes encoding the M, NP, P, or L proteins. However, the mutations primarily constitute minor nucleotide shifts and/or amino acid changes and do not amount to function nullifying or expression silencing modifications. In contrast, the claimed invention requires either "deletion" or "inactivation" of the noted Sendai viral gene(s). Accordingly, since the Middleton mutants do not involve deletion

or inactivation of one or more of the NP, P, or L genes, the Middleton reference can neither anticipate nor render obvious the invention of claim 27.

Thus, Applicants respectfully request reconsideration and withdrawal of these rejections in view of the amendments and remarks presented herein.

Conclusion

In sum, Applicants respectfully submit that the response herein fully addresses rejections set forth in the outstanding Office Action. Applicants submit that claims 1, 4-13, 15-18, 20, 22, 27, and 28 presented herein are in condition for allowance and respectfully petition for an early notice of allowance. In any event, if the Examiner believes a conference would expedite prosecution, she is cordially invited to contact the undersigned.

Respectfully submitted,

Date: 05-04-09

By: _____

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Dictionary of Gene Technology

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Activator RNA: The hypothetical transcript of an → integrator gene that binds to a → receptor gene and activates one or several specific sets of genes (Britten-Davidson model).

Active gene: Any → gene that is transcribed into a → ribosomal RNA, → transfer RNA, or → messenger RNA. Compare → cryptic gene.

Adaptation: Any change of the structure and/or function of an organism that enables it to better cope with changing environmental conditions.

Adapter primer (AP): A synthetic → oligodeoxynucleotide that functions as a → primer for e.g. → reverse transcriptase or as → amplimer in the → polymerase chain reaction, and additionally carries one or several → restriction endonuclease sites. Adapter primers are used for e.g. → rapid amplification of cDNA ends.

Adaptor (adapter, oligonucleotide adaptor):

a) A short synthetic → oligonucleotide with a preformed cohesive terminus. Such adaptor molecules are used to join one DNA duplex with → blunt ends to another DNA duplex with → cohesive ends. In short, the adaptor possesses one blunt end with a 5' phosphate group and a cohesive end which is not phosphorylated (to prevent → self-ligation). The adaptor is ligated to the blunt-ended DNA target fragment and the construct phosphorylated at the 5' termini with → polynucleotide kinase. Then the hybrid molecule is ligated into a corresponding → restriction site of the second DNA molecule (usually a vector). See for example → Eco RI adaptor ligation.
b) See → adaptor hypothesis.
c) Adaptor RNA: See → transfer RNA.
d) Adaptor (mediator): A nuclear protein that does not bind to DNA but mediates the interaction of other proteins with DNA.

Adaptor hypothesis: The theoretical requirement of a mediator ("adaptor") between the information-carrying → messenger RNA molecule and the protein it codes for. This adaptor should be able to recognize both kinds of molecules. The adaptor hypothesis was verified by the discovery of → transfer RNA (tRNA) and the corresponding → aminoacyl-tRNA synthetases.

Adaptor RNA: See → transfer RNA.

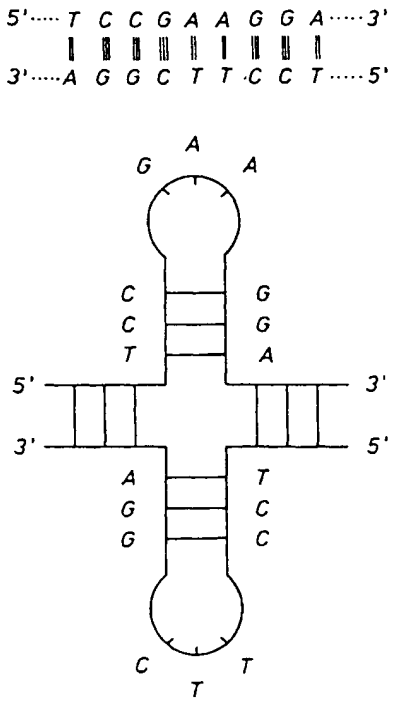
Additive recombination: Any → insertion of a new DNA sequence into an existing genome without the reciprocal loss of DNA (e.g. the insertion of → insertion sequences, the insertion of → transgenes).

Add-on sequence (5' add-on sequence): Any → restriction endonuclease recognition sequence that is attached to the 5'end of either one or both → oligonucleotide primers (see also → oligo(dT) priming) used in the → polymerase chain reaction. These sites facilitate the insertion of the amplified fragments into corresponding restriction sites in → cloning vectors. Other sequences can also be used as add-on sequences (e.g. → RNA polymerase promoters that allow transcription of the amplified sequences). See for example → PCR add-on primer.

Address site: See → recognition sequence.

Ade: *Ade*nine, see → A.

***A*denine:** See → A.



Cruciform configuration: See → cruciform.

Cruciform DNA: See → cruciform.

Cryptic gene (inactive gene; silent gene): Any → gene that is not expressed. Compare → active gene.

Cryptic plasmid: A → plasmid which has no phenotypical effect on the bacterial host.

Cryptic promoter: Any → promoter that is located close to a genomic site where foreign genes are inserted and allows the transcription of these genes.

Cryptic satellite: A → satellite DNA fraction that is only a minor component of a cell's genome and has roughly the same buoyant density as bulk chromosomal DNA, so that both fractions are banded together in CsCl buoyant density gradients (see → isopycnic centrifugation). In some cases these cryptic satellites can be separated from the bulk DNA by Cs_2SO_4/Ag^+ or Cs_2SO_4/Hg^{2+} centrifugation. They may also be detected by the rapid reannealing behavior of their highly repeated sequences in → C_0t analysis experiments.

Cryptic splice site: A → splice junction that is located within an → intron and may be used for → splicing of mRNA, if the normal splice junctions are mutated, deleted, or otherwise non-functional. Cryptic splice sites may also be used for the generation of different mRNAs from the same DNA sequence in → alternative splicing.

Cryptic virus: Any → virus or virus-like particle that does not cause symptoms in infected plants. Some cryptic viruses contain dsRNA (e.g. beet cryptic virus).